The CodeX HL7 FHIR Accelerator

A Member-driven community accelerating interoperable data modeling and implementation around the FHIR and mCODE HL7 standards, leading to substantial improvements in health care and research

http://hl7.org/CodeX
Contents

• Introduction to CodeX HL7 FHIR Accelerator
  • HL7 FHIR Accelerator Community building real-world, interoperable implementations across oncology, cardiovascular medicine and genomics

• Use Cases in 3 Domains
  • Oncology Domain
  • Cardiovascular Domain
  • Genomics Domain

• Membership and Governance
CodeX announced at HL7/Atlanta (Sep 2019) and brainstormed first Use Cases at the Cancer Data Summit (Oct 2019)
What is a FHIR Accelerator?
“...designed to assist communities .. across the global health care spectrum in the creation and adoption of high quality FHIR Implementation Guides .. to move toward the realization of global health data interoperability”

https://www.hl7.org/about/fhir-accelerator/

HL7 FHIR Accelerators
1 Accelerator = Multiple Clinical Specialties

HL7 FHIR Accelerator

Oncology Domain
mCODE™

Cardiovascular Domain
CardX™

Genomics Domain
GenomeX™

New!
Most of the nearly 15 million individuals living with cancer in the U.S. have **Electronic Health Records (EHRs)**

**EHR data challenges:**
- Distributed
- Significant variation
- Unstructured
- High Burden
- Difficult to access and share

**Swivel-chair interoperability**

Credit: Tcheng
Vision & Data Strategy

Collect patient data once.

Structured, actionable, clinical data defined by FHIR Implementation Guides

Use and reuse directly for ...

- Care of the patient today.
- Health of the patient for a lifetime.
- Ensuring that one patient’s journey improves care for all future patients.
CodeX

Work & Impact Strategy

1. Welcome!
   ...a motivated **Community** of key stakeholders necessary for success

2. Prioritize
   ...**Use Cases** around community commitment and potential to improve **patient care** and **research**

3. Build
   ...core, standard **FHIR IGs** (ex: mCODE) and supplemental IGs

4. Implement
   ...standards into real **products**, systems and new workflows

5. Execute
   ...**Pilots** in the field with **patients**, **providers** and other future **users** to **demonstrate impact** and feasibility, and enable rapid **adoption** and scaling
A growing group of health systems and other key stakeholders, learning together in a monthly public forum focused on real-world applications of mCODE and new areas of interest around information technology applications across oncology, cardiovascular, and genomics.

- Latest developments on mCODE, CodeX, and cancer data exchange
- Ask questions and learn from the experience of other community participants
- Develop and share best practices for clinical workflows, data modeling, and exchange
CodeX Members
(September 2022) CodeX Founders

PREMIER

AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE
ASTRO
HL7 International
Pfizer
ALIANCE FOR CLINICALS & ONCOLOGY

PRINCIPAL

Cancer Action Network
VARIAN
A Siemens Healthineers Company

BENEFACTOR

MITRE
EVERNORTH
Syntropy
ontada
UnitedHealthcare

GOVERNMENT AGENCY

U.S. FOOD & DRUG ADMINISTRATION
University of Nebraska Medical Center
MCSP MICHIGAN

SPONSORED MEMBER

COMPS
ONCPM
NRG ONCOLOGY
SIIM

DEVELOPER/IMPLEMENTER

Cancer Insights
elimu Informatics
MASSIVE
MCGr Mettle Solutions
Navigate Oncology
NeuralFrame

Oncora Medical
patientlink
PHENOTIPS
PRINCIPIA HEALTH SCIENCES

Quantum Leap Healthcare Collaborative
Wemedoo
Clinical Immunization Specialists
Use Case Development and Transition Guidelines

https://confluence.hl7.org/display/COD/Use+Case+Development+Guidelines

**Discovery**

- Pre-Discovery
- Use Cases

**Members, Potential Members, Thought Leaders**

**Planning**

- Use Case Backlog
- Proposed Use Cases:
  - # 1
  - # 2
  - # 3
  - #N

**Selection**

- Members and orgs with written commitment to join work together on Use Case Discovery and Planning

**Execution**

- Steering Committee
- Led by Members, with regular public meetings
- Build/improve FHIR IGs, Implementation in systems, Pilots, Adoption, Scale

**Concept and Impact**


**Team**

Members. Commitments.

**Plan**

Phases. Implementation. Adoption.

**Multi-Phased Approach**

- Scale to widespread adoption of interoperable Patient Clinical Trial Mastering standards / open APIs

- Assess preparation for Execution and any resource requests, based on plan and discussions
CodeX Use-Cases

https://confluence.hl7.org/display/COD/CodeX+Use+Cases

Oncology
- mCODE++ Extraction
- EHR Endpoints for Cancer Clinical Trials
  (including, future extensions of the ICAREdata study)
- Integrated Trial Matching for Cancer Patients and Providers
- Cancer Registry Reporting
- Radiation Therapy Treatment Data for Cancer
- Prior Authorization in Oncology
- Risk Evaluation and Mitigation Strategies (REMS)
- Oncology Quality Measures

Cardiovascular
- CardX - Hypertension Management

Genomics
- GenomeX - Genomics Data Exchange
- GenomeX - Genomics Operations

Stages
- Discovery
- Planning
- Execution

CardX
GenomeX
mCODE™
Potential New CodeX
Oncology Use-Cases Under Discussion

- Structuring inclusion and exclusion trial matching criteria
- Regulatory grade RWE
- Oncology nurse case manager

- Internationalization of mCODE (not necessary a "use case", but could be tied to one)

- Oncology Clinical Pathways (hibernating – awaiting community interest)
Better, standardized data improves care *quality* and *equity*

- Better outcomes for all
- Diversification in clinical trials
- Ability to analyze standardized RWD across populations
- Monitoring of safety and efficacy of approved therapies
- Public health surveillance
- Prior authorization processes in oncology
People’s lives are depending on what we do and what this data tells us.

DR. MONICA BERTAGNOLLI
Chief of Surgical Oncology, Dana-Farber Cancer Institute/Brigham and Women’s Hospital
Professor of Surgery, Harvard Medical School
President, Alliance for Clinical Trials in Oncology

mCODE™

... where it all started

CodeX™
VP @JoeBiden discusses #mCODE - our collaboration w/ @ASCO to create a new data standard to improve cancer research & treatment - at today's @BidenCancer update on progress against cancer bit.ly/2HGpZ3
#MITREhealth Learn more: health.mitre.org/mcode/

https://www.youtube.com/watch?v=AKklpOnuSCE&feature=youtu.be
minimal Common Oncology Data Elements

A FHIR-based core set of common data elements for cancer that is standardized, computable, clinically applicable and available in every electronic health record for patients with a cancer diagnosis

A standard health record for oncology

The minimal set of data elements applicable to all cancers, and collected for:

- Standardized information exchange
- Use-case driven and targeted use

Oncology data element domains: patient, disease, treatment, outcomes, genomics, lab/vital

mCODE STU2: http://hl7.org/fhir/us/mcode/
Building an Engaged Network of Health System Solutions

Brigham and Women’s Hospital
City of Hope
Dana Farber Cancer Institute
Duke University
Heartland Cancer Research
Massachusetts General Hospital
McGill University
MD Anderson Cancer Center
Metro-Minnesota Community Oncology
Missouri Baptist
Northwell Health
Rush University Medical Center
Saint Joseph Mercy Health System
The Ohio State University
The University of Chicago Medicine
ThedaCare
Trinity Health
UNC Lineberger Comprehensive Cancer Center
University of California San Francisco
University of Kansas Medical Center
University of Michigan
University of Pennsylvania
University of Texas Southwestern
Veterans Health Administration
Virginia Commonwealth University
Wake Forest University
Washington University in St Louis

Oncoclinicas
Taiwan Cancer Registry
Netherlands Cancer Registry
UC Los Angeles
Mayo Clinic

Scaling through Industry Implementations

CancerInsights
Cerner
Clinical Pipe
Elekta
Elsevier
Epic
Flatiron
IQVIA
Jitterbit
MassiveBio
Mettle Solutions
Microsoft
NeuralFrame
Nuance
PatientLink
Pfizer
RaySearch
Roche
Semedy
Syntropy
Trial Scope
TrialJectory
Varian
Varian
Wemedoo

Engaged & Previously Expressed Interest – Engaged in multiple conversations and/or in the process of being Active

Active – Committed or actively participating in planning, design, development, piloting
Oncology Use Cases
mCODE++ Extraction
CHALLENGE
• Structured patient outcomes are not available in the EHR to support real world evidence, limiting participation and impact of clinical trials

OPPORTUNITY
• Enable investigators to leverage clinical treatment data captured in the EHR to expand participation in clinical research
• Build the foundation to transform clinical trials and cancer research by enabling unprecedented inferences across populations

DESIRED IMPACT
✓ Clinical treatment data captured in the EHR to derive trial endpoints
✓ Generate research quality data for standard of care patients in the routine care setting
✓ Expand participation in clinical trials
✓ Enable generalizability studies to compare clinical trials cohorts for expanded insights
ICAREdata® Multi-Phase Approach

**Goal**
Support the collection electronic health record (EHR) data, based on mCODE, to broaden participation in clinical oncology research.

**Phase 1**
Validation of the Methodology
- Disease Status
- 5 sites, 2 trials
- 96% Concordance with 95% probability when disease absent

**Phase 2**
Clinical Events and National Scale
- 25+ sites
- 11+ trials

**Phase 2+**
Alignment with Sponsor Objectives
- Funding to support operations and adverse events
- Additional interest to expand

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96% Concordance with 95% probability when disease absent
Integrated Trial Matching for Cancer Patients and Providers

Problem
• Patients are not made aware of clinical trial opportunities outside of their treating institution

Solution
• Create integrated, automated, site-agnostic clinical trial matching by developing open data standards and APIs that enable interoperable, scalable, and accessible clinical trial matching services

Desired Impact
• Patients and providers can easily identify potentially lifesaving therapies much faster with tools that leverage structured data from the EHR
• Researchers can find more patients for their clinical trial
Multi-Phased Approach

Phase 0
- Standards Development – demonstration of this capability
- Demonstration and Documentation – https://confluence.hl7.org/display/COND/Phase+0

Phase 1
- Retrospective Study – validation of optimized patient data elements
- Results – https://confluence.hl7.org/display/COND/Phase+1
- Presentation Summary - https://confluence.hl7.org/display/COND/Trial+Matching+Meetings

Phase 2
- Prospective Study – integration with health site EHR and PDM application
Integrated Trial Matching for Cancer Patients and Providers (Update as of September 2022)

Project Updates

• **Phase 2**: demonstrate value through a prospective pilot where the capability is integrated at a health site and in a PDM application.

Research aims:

• Overall clinical trial enrollment
• Demographic diversity of trial enrollment
• Impact of navigation and support
• Analysis of usability

• ACS CAN received a $1M grant by Amgen to support a multi-site pilot
Cancer Registry Reporting

Problem
• Clinical data is stored in disparate systems in multiple data formats
• Variability in data collection processes imposes a high burden on data reporters and negatively impacts understanding of patient care
• Heterogeneity of data collection makes it difficult to aggregate and share data for use in clinical research and standards of care

Solution
• A low-burden, standardized reporting of cancer data from cancer centers to registries that are aggregating data for different reasons

Desired Impact
• As a patient begins and continues cancer care, outcomes are tracked, and effectiveness of care is determined in real time and reported in a low burden and interoperable manner
• Reduce reporting burden and enhance insights into clinical practice
Cancer Registry Reporting
(Update as of December 2021)

We are here

Phase 0
Pilot Activity
Proof of concept
California focused proof of concept with UCSF, CA Cancer Registry, CIBMTR. Using CDC’s MedMorph IG and reference architecture to send synthetic data to a state and private registry.

Phase 1
Extended Elements and Testing
Further utilize mCODE
Operationalize CIBMTR data exchange at UCSF
Explore rapid case ascertainment
Develop primary/secondary case reporting approach with registry reporting software org.
Metric measurement

Phase 2
Transition From Test to Production
Review lessons learned from phase 1
Measure outcomes
Build implementation processes
Increase the number of health systems
Increase the number of registries
Radiation Therapy Treatment Data for Cancer

**Problem**
- Treatment details – critical for care coordination – are not readily available in systems other than radiation oncology EHR modules: data is generally manually entered into summary documents, creating clinical burden and potential patient safety issues

**Solution**
- To develop, test and deploy open data standards that enable interoperable, multi-purpose exchange of radiation treatment summary data for care coordination and data reuse

**Desired Impact**
- Enable sharing of critical radiation therapy treatment data for care coordination or data reuse (research, quality measurement, payer-required reporting)
Radiation Therapy Treatment Data for Cancer
(Update as of August 2022)

- **Phase 0**: Standards Development – mCODE radiotherapy

- **Phase 1**: Proof of Concept – End of treatment summary
  - XRTS Workshop Results: [https://confluence.hl7.org/display/COD/RTTD+Phase+1](https://confluence.hl7.org/display/COD/RTTD+Phase+1)

- **Phase 2**: Proof of Concept – In-progress treatment summary
  - XRTS Workshop Results: [https://confluence.hl7.org/display/COD/RTTD+Phase+2](https://confluence.hl7.org/display/COD/RTTD+Phase+2)

- **Phase 3+**: Pilot Study – End-to-end workflow of RT summary
  - Prepare for another XRTS Workshop – December 2022
  - Define the Pilot Design between a vendor system and health site EHR
Prior Authorization in Oncology

**Problem**
- Prior authorization imposes a burden on patients, providers, and payers
- Prior authorization documentation requirements vary by payer plan
- Current manual processes are costly and may delay treatment

**Solution**
- Reduce clinical burden when requesting oncology treatment regimens by building on Da Vinci CRD/DTR/PAS specifications to supplement prior authorization request with mCODE data elements.

**Desired Impact**
- Develop automated prior authorization capability in which 80% of approvals do not require manual inspection

**Da Vinci Exchange**
- Implementing this use case in oncology produces the standardized exchange for use in any specialty or other PA services or procedure.
Prior Authorization in Oncology – Planning Phases
(Updated as of August 2022)

Collaborators

Framework -Proof of Concept

- Proof of concept for breast cancer and colorectal cancer prior authorization
- Demonstration of the Da Vinci CRD/DTR/PAS IGs working in a medical oncology flow
- Test and demonstrate use of adaptive forms in questionnaires to show variations and flexibility of trigger (encounter, order)
- Document scenarios and open-source code for the questionnaires and CQL

Prior Authorization in Oncology Supporting Materials

Rad ONC Prior Auth Proof of Concept for Prostate Cancer (MVP)

- Design – Validate workflows, define process and requirements, includes demographic and patient clinical data elements
- Build & test the exchange of prior authorization between provider and payer systems using EHR test patients
- Evaluate lessons learned and rescope iteratively
- Implementation into production environment
- Use of mCODE data elements in PA transactions
- Demonstrate PA transactions in the FHIR-based Da Vinci CRD/DTR/PAS information exchange

Prior Authorization Pilot

- Scale
- Advance and apply lessons learned from Phase 1 (MVP)
- Add additional cancer types
- Expansion consideration into medical oncology and progress into modality sequencing
- Add additional participating organizations (Payer, Provider, Oncology EHR)
Risk Evaluation and Mitigation Strategy (REMS)
A drug safety program that FDA can require for certain medications with serious safety concerns to help ensure the benefits of a medication outweigh its risks

Goal of the CodeX REMS Integration Use Case
Create an automated, efficient, and effective REMS ecosystem with a standards-based technical infrastructure for REMS integration into workflow, enabling data sharing and reducing undue burden
Cardiovascular Use Case
New Cardiovascular Domain Hosting Multiple Use Cases

Questions
• Can a medical specialty in addition to oncology ...
  • Follow the CodeX / mCODE approach (and faster)?
  • Create a minimal Cardiovascular FHIR IG that is consistent and interoperable with mCODE?
  • Leverage work of oncology use cases (e.g., RWD trials, trials matching, registry reporting)?
  • Improve cardiovascular patient care and research

Plans
• University of Nebraska, leading
• Leveraging previous work on minimal data elements
• Gathering interested members of the community
• Identifying potential first Use Cases
  • Hypertension is of particular interest
Genomics Use Cases
Problem

Most genomic tests are currently sent from the laboratory to health care organizations in the form of a PDF or in a limited discrete proprietary format unique to the reference lab, isolating this non-computable information within the EHR, and inhibiting its use for clinical care and research.

Solution

Use Case members will determine the initial types of genomic reporting to focus on.

They will then develop scenario-based profiles/import specifications leveraging the FHIR Genomics IG to develop communication of structured genomic data from a laboratory to a receiving organizations EHR or genomic data repository.
Members who are part of the Use Case will determine the initial types of genomic reporting to focus on. They will then develop scenario-based profiles/import specifications leveraging the FHIR Genomics IG to develop communication of structured genomic data from a laboratory to a receiving organizations EHR or genomic data repository.

Discovery Phase
Currently building community, identifying specific problems and solutions, and identifying technical leads to move work forward.

Desired Impact
• Increase the interoperability of genomic data and from the EHR, freeing its use for clinical care and research.
• Allow stakeholders to analyze real-world data from large cohorts of patients.
• Facilitate informed treatment decisions between clinicians and patients, new research, and the development of clinical decision support tools.
Problem

- Without comprehensive and continuously updated clinical knowledge tied to ever-evolving genomic findings, providers are overwhelmed.
- EHRs are not designed to manage such a large volume of results.

Solution

- FHIR Genomics operations are based on the premise that an organization’s genomic data is stored in a repository either in or alongside an EHR.
- This data may be stored in FHIR format and/or alternate formats (e.g. VCF format).
- FHIR Genomics operations ‘wrap’ the repository, hiding its complexity, and present a uniform interface to developers.
An initial introduction meeting has been held with the Use Case members and other interested community members. An overview Genomic Operations and their current capabilities (based on the reference implementation) was shared. The next meeting will begin to drill down into the initial focus of the use case and its timeline.

**Discovery Phase**
Currently building community, identifying specific problems and solutions, and identifying technical leads to move work forward.

**Desired Impact**
- FHIR Genomics Operations ease the development and population of data for many types of applications including SMART-ON-FHIR clinical genomics apps, Clinical Decision Support, and EHR visualizations.
Membership and Governance
Program Management
Cross-Program Support Options: Governance Support, Use Case Meeting Support, Architecture, Informatics, Membership Engagement, Communications, Education, Implementation

Steering Committee
(elected by Operating Committee)

Operating Committee
(1 representative from Paying, Government and Sponsored Members)

Use Case 1
Use Case 2
Use Case 3
Use Case n+

Community of Practice

External Expert Groups

WG & other Accelerators

HL7 International
# CodeX Membership Categories

[https://confluence.hl7.org/display/COD/CodeX+Membership+Options](https://confluence.hl7.org/display/COD/CodeX+Membership+Options)

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<th>Level</th>
<th>Annual Membership Fees</th>
<th>Operating Committee Vote</th>
<th>Sponsor Partner Operating Committee Membership</th>
<th>Participate in Use Case Leadership Calls</th>
<th>Invited to Use Case Workgroup Calls</th>
<th>Pledge Resources</th>
<th>Access to Use Case Artifacts</th>
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**Notes:**
- *Premier and Principal Members may nominate partner organizations to join the Operating Committee (proxy membership) and must be approved by the Steering Committee.
- **Developer/Implementer Members must be approved by the Steering Committee based on their commitment to contribute resources to implement CodeX products and support Use Cases. Developer/Implementer Members with >$50M in annual revenue will be asked to join as a paying Member after the first year of membership. Companies with revenues <$50M may continue as Developer/Implementer Members for as long as they are contributing to CodeX work.
- All CodeX Members sign the standard Statement of Understanding/Member Agreement. This document is the standard used by HL7 and is similar to the document signed within other HL7 FHIR Accelerators.
- Membership as a Founder was open to those who joined at the Premier level before the end of 2020.
- Health systems may participate in CodeX pilots and related planning calls free of charge. Health systems that want to participate in CodeX decision-making may seek to join as Paying, Government or Sponsored Members.
CodeX Member Benefits

Governance & Oversight

- Paying, Government and Sponsored Members have a seat on the Operating Committee
  - Premier Members may also run for the decision-making Steering Committee

Use Case Leadership

- Paying, Government and Sponsored Members (and those who commit to join at one of these levels) may serve on Use Case Leadership Teams, responsible for developing project plans, engaging partners, and overseeing work that includes transforming domain knowledge to FHIR-based models, implementing these within software and piloting to demonstrate the art of the possible
  - Recognized as leaders through CodeX thought leadership, conference key notes, press quotes, logos on websites and slides, etc.

Community Building & Access

- Premier and Principal Members may sponsor other organizations to become CodeX Members
- Learn in a committed community and gain early access to and achieve deeper understanding of FHIR implementations
Opportunities
Excitement Ahead!

- Evolution of oncology, cardiovascular, genomics domains
- Additional clinical specialties?
- ARPA-H?
- White House Cancer Moonshot?
- Philanthropic fundraising (re-vamped FHIR Foundation is key)
A Member-driven community accelerating interoperable data modeling and implementation around the FHIR and mCODE HL7 standards, leading to substantial improvements in health care and research in cancer, cardiovascular, genomics and beyond.

https://www.hl7.org/codex/
https://confluence.hl7.org/display/COD/CodeX+Home

Please let us know how we can help …

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